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14	IN THE UNITED STATES DISTR
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15	FOR THE DISTRICT OF AR

## RICT COURT

#### RIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. 2:15-MD-02641-DGC

**DEFENDANTS' AMENDED** ION AND INCORPORATED MEMORANDUM TO SEAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") hereby respectfully move this Court for an order sealing certain documents accompanying Bard's Motion and Memorandum in Support of Motion for Summary Judgment Regarding Preemption. The documents that are the subject of Bard's Motion to Seal constitute trade secrets or other confidential research, development, or commercial information concerning Bard's interactions with FDA about Bard's line of optional IVC filters. Protecting such information from public disclosure and from Bard's competitors will prevent Bard from sustaining serious economic and competitive harm, thereby representing a compelling reason to protect the documents' confidentiality. Accordingly,

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the Court should grant Bard's Motion to Seal.

#### **ARGUMENT AND CITATION OF AUTHORITY**

Although the Ninth Circuit has recognized that the public has a "general right to inspect and copy public records and documents, including judicial records and document," *Kamakana v. City & Cnty. of Honolulu*, 447 F.3d 1172, 1179 (9th Cir. 2006) (quoting *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 597 & n. 7 (1978)), it has also recognized that the right of public access is not absolute and is overcome for materials that "have traditionally been kept secret for important policy reasons." *Id.* (quotation omitted).

Such compelling reasons for sealing documents exist, for example, regarding proprietary, trade secret, and technical information about FDA submissions—the same type of information that Bard requests that the Court seal here. For example, in *In re* Incretin-Based Therapies Products Liability Litigation, No. 13MD2453 AJB (MDD), 2015 WL 11658712 (S.D. Cal. Nov. 18, 2015), the Court considered motions to seal related to cross-motions for summary judgment on the affirmative defense of preemption. The court found that compelling reasons existed to grant the motions to seal because the documents were "confidential and proprietary information specific to each drug at issue and the development, testing, and regulation of each drug." *Id.* at \*3. The court found that such information "is readily subject to improper use resulting in significant competitive harm if disclosed publicly and available to competitors." Id. Moreover, because the court's analysis in resolving the underlying motions focused on FDA action, as opposed to an "evaluation or analysis of the specific data considered by the FDA," disclosing the information publicly "would shed no light on the judicial process and bears the risk of causing confusion to the public through the limited disclosure of traditionally confidential data and regulatory submissions." Id.

Similarly, in *Spectrum Pharmaceuticals, Inc. v. Sandoz Inc.*, No. 2:12-CV-00111-GMN, 2014 WL 4202540, at \*2 (D. Nev. Aug. 21, 2014), the court considered documents submitted in support of Sandoz's motion for summary judgment. The documents related to an Abbreviated New Drug Application to the FDA, technical information about the

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product, and specific efforts to obtain FDA approval of the Application, including actual and planned confidential communications with the FDA. Id. The court found that documents of this nature could injure the parties' business, thereby constituting a compelling reason to grant the motion to seal. *Id.*<sup>1</sup>

The documents that Bard seeks to seal in support of its Bard's Motion and Memorandum in Support of Motion for Summary Judgment Regarding Preemption are the same kinds of documents that the *In re Incretin-Based Therapies* and *Spectrum* Pharmaceuticals courts sealed at the dispositive motions stage. Bard's documents reflect confidential and proprietary information concerning the design, development, testing (including clinical testing), manufacture, and regulatory compliance activities concerning Bard IVC Filters; 510(k) submissions, IDE submissions, and other materials sent to FDA that detail Bard's product development activities, proprietary testing, and implementation of various proprietary processes and procedures; contact reports and e-mail communications, which likewise contain information Bard's product development activities, proprietary testing, and implementation of various proprietary processes and procedures; and communications from FDA, which frequently contain questions that detail and disclose Bard's product development activities, proprietary testing, and implementation of various proprietary processes and procedure.<sup>2</sup> Decl. of Rob Carr ¶¶ 132-37, Mar. 23, 2017, attached as Exhibit A to Bard's Separate Statement of Facts in Support of Bard's Motion for Summary Judgment Regarding Preemption. documents took years for Bard to develop and they reflect Bard's critical and confidential

<sup>&</sup>lt;sup>1</sup> See also JL Beverage Co., LLC v. Beam, Inc., No. 2:11-cv-00417-MMD-CWH, 2013 WL 1088363 (D. Nev. Mar. 14, 2013) rev.'d on other grounds, 828 F.3d 1098 (9th Cir. 2016) (finding compelling reasons to seal exhibits to motion for summary judgment that concerned "sales figures, advertising numbers, and strategy information relating to Defendants' Pucker Vodka line of products"); Selling Source, LLC v. Red River Ventures, LLC, 2:09-CV-01491-JCM, 2011 WL 1630338, at \*6 (D. Nev. Apr. 29, 2011) (finding compelling reasons to seal documents concerning business operations, customer agreements, corporate structure, and the details of the plaintiff's customer base and interactions with customers); Clark v. Metro. Life Ins. Co., No. 3:08-cv-00158-LRH-VPC, 2010 WL 1006823 (D. Nev. Mar. 16, 2010) (finding compelling reasons to seal "confidential internal business deliberations, organization, and capabilities").

<sup>&</sup>lt;sup>2</sup> A more detailed listing of each document at issue is attached as Exhibit A.

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business information. *Id.* Moreover, the documents would be of economic value to Bard's competitors, not just for IVC filters, but also to manufacturers of other medical devices, as the information contained in the documents is not limited to IVC filters. *Id.* Bard invests substantial amounts of money in medical device research, testing, clinical trials, development, design, analysis, regulatory compliance, evaluation, and marketing. Id. Thus, if Bard's competitors obtained these documents, they would have an unfair economic advantage over Bard. Id.

Therefore, compelling reasons exist for protection of Bard's documents, and the Court should grant Bard's Motion to Seal.

#### CONCLUSION

For the foregoing reasons, the Court should grant Bard's Motion to Seal.

DATED this 24th day of March, 2017.

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#### **CERTIFICATE OF SERVICE**

I hereby certify that on March 24, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/ Richard B. North, Jr.